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Claude Mialhe

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EXAMINER

DANG, PHONG SON H

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,173	Applicant(s) MIALHE, CLAUDE	
	Examiner SON DANG	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-13 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-13 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05/16/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 01/21/2009 has been entered. Claims 6 and 14-15 have been cancelled. Claims 16-18 have been added. Claims 1-5, 7-13 and 16-18 are currently pending in the application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1- 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US PG PUB 2001/0037053 to Bonadio et al. (Bonadio).

In Reference to Claim 1:

Bonadio teaches:

Avascular occlusion device (1, Fig. 1) comprising a hollow cylindrical element (outer sleeve 11 (a), Fig. 2) that can be twisted (outer sleeve 11 is capable of twisting since the inner sleeve is twisting (Fig. 5, page 3, paragraph 83, lines 8-10)) to its axis to create a striction zone, comprising a transverse compression deformable body (the inner sleeve of 1 l(b), Fig. 2) applied to the inner wall of the cylindrical element (the inner sleeve 11 (b) is inside of the outer sleeve 11 (a), Fig. 2), and comprising a through hole (12, Fig. 5, page 3, paragraph 83, lines 8-10) according to axis of the cylindrical element (11, Fig. 1).

In Reference to Claim 2:

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Bonadio teaches:

The device according to claim 1 (see rejection of Claim 1 above), wherein the eformable body (the inner sleeve of 1 I(b), Fig. 2) is attached to the inner wall of the cylindrical element (outer sleeve 11 (a), Fig. 2).

In Reference to Claim 3:

Bonadio teaches:

The device according to claim 1 (see rejection of Claim 1 above), wherein the deformable body (the inner sleeve of 1 I(b), Fig. 2) is made from a polymer material (page 3, paragraph 84, lines 4-5).

In Reference to Claim 4:

Bonadio teaches:

The device according to claim 1 (see rejection of Claim 1 above), comprising two end parts (10 and 21, Fig. 4, page 3, paragraph 84, lines 7-9), surrounding the cylindrical element (outer sleeve 1 I(a), Fig. 2) and whose angular position determines the torsion (Any angle inherently determines the torsion) of said cylindrical element (11, Fig. 5).

In Reference to Claim 5:

Bonadio teaches:

The device according to claim 1 (see rejection of Claim 5 above), wherein cylindrical element (outer sleeve 1 I(a), Fig. 2) and the deformable body (the inner sleeve of 1 I(b), Fig. 2) both have circular cross sections (They both have cylindrical body therefore both inherently have circular cross sections).

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In Reference to Claim 7:

Bonadio teaches:

The device according to claim 5 (see rejection of Claim 5 above), comprising two end parts (10 and 21, Fig. 4, page 3, paragraph 84, lines 7-9), surrounding the cylindrical element (outer sleeve 1 I(a), Fig. 2) and whose relative angular position determines the torsion (any angle inherently determines the torsion) of said cylindrical element (outer sleeve 1 I(a), Fig. 1), said end parts (10 and 21, Fig. 4, page 3, paragraph 84, lines 7-9) possessing means of attachment to the wall of a vessel.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonadio in view of US Patent No. 5,843,160 to Rhodes (Rhodes).

In Reference to Claim 8:

Bonadio teaches:

The device according to claim 7 (see rejection of Claim 7 above).

Bonadio fails to teach:

The device wherein the attachment means are expanding elements.

Rhodes teaches:

The device (20, Fig. 1) wherein the attachment means are expanding elements (34, 36, Fig. 1, Col. 8, line 25).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the expanding element of Rhodes in place of the Bonadio attachment means because the modification would have been considered a mere substitution of attachment means.

In Reference to Claim 9:

Bonadio as modified by Rhodes teaches:

The device according to claim 8 (see rejection of Claim 8 above).

Rhodes teaches:

The device (20, Fig. 1) comprising a seal (30, Fig. 1, Col. 9, lines 34-41) on the outer surface of at least one of the expanding elements (36, Fig. 1, Col. 8, line 25) said seal being appropriate for application to the wall of a vessel.

In Reference to Claim 10:

Bonadio as modified by Rhodes teaches:

The device according to claim 8 (see rejection of Claim 8 above), comprising a peripheral obturation web (Fig. 26, after the inner sleeve 210 get twisted, it formed a funnel like shape) extending from one end of the deformable body (Fig. 26, the edge that is proximal to O-ring 205) and the edge (Fig. 26, the edge that is proximal to O-ring 210) of the expanding element (201, Fig. 26).

6. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonadio in view of US Patent No. 7,008,439 to Janzen et al. (Janzen).

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In Reference to Claim 11:

Bonadio teaches:

The device according to claim 1 (see rejection of Claim 1 above).

Bonadio fails to teach:

The device comprising a removable guide positioned according to the axis of the cylindrical element and crossing the hole in the deformable body.

Janzen teaches:

The device comprising a removable guide (15, Fig. 14, Col. 4, line 49) positioned according to the axis of the cylindrical element (Fig. 15, the sleeve cover sheath 45) and crossing the hole (Fig. 15, diameter of sheath 45) in the deformable body (45, Fig. 15, Col. 5, line 7).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the removable guide as taught by Janzen in the device of Bonadio for the benefit of guiding of the position for the occlusion device.

In Reference to Claim 12:

Bonadio as modified by Janzen teaches:

The device according to claim 11 (see rejection of Claim 11 above).

Janzen teaches:

The device comprising a removable sheath (17, Fig. 15, Col. 4, line 49) inserted between the wall of the hole (Fig. 15, diameter of sheath 45) in the deformable body (45, Fig. 15, Col. 5, line 7) and the outer wall of the guide (15, Fig. 14, Col. 4, line 49).

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In Reference to Claim 13:

Bonadio teaches:

The device according to claim 1 (see rejection of Claim 1 above).

Bonadio fails to teach:

The device comprising a removable sleeve surrounding the occlusive device.

Janzen teaches:

The device comprising a removable sleeve (Fig. 15 & 20, the sleeve covering sheath 45) surrounding the occlusive device (plug 93, Fig. 17, Col.8, line 64).

It would be obvious to one having ordinary skill in the art at the time of the invention to have used the sleeve of Janzen for containing and delivering of the occlusive device of Bonadio because the modification would have facilitated implantation of the occlusive device of Bonadio.

7. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonadio in view of US Patent No. 6,168,619 B1 to Dinh et al. (Dinh).

In Regard to claims 16-18:

Bonadio teaches:

The device according to claims 1, 3 and 8 (see rejections of claims 1, 3 and 8 above), wherein a frame having a first central zone constituting the cylindrical element and two zones around the first zone, said two zones constituting expanding elements.

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Bonadio fails to teach:

The polymer material has shape memory properties. The expanding elements are self-expanding frames. A Nitinol based metallic frame.

Dinh teaches:

The polymer material has shape memory properties. The expanding elements are self-expanding frames. A Nitinol based metallic frame (Col. 1, lines 12-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the frame of Dinh into Bonadio in order for sustain the self-expanding and shape memory properties for the frame as it is well known in the art to reduce time during a procedure.

Response to Arguments

8. Applicant's arguments filed 01/21/2009 have been fully considered but they are not persuasive. In Regard to the 35 USC 102 rejections, the applicant argued on page 6 of the Remarks that the device of Bonadio did not teach for vascular use. This is not persuasive because all the structures in the claim limitations are anticipate with Bonadio's. Therefore, as the 35 USC 102 rejections are concern, if all the structure limitations are met, the device is capable of performing the same function. Bonadio's are capable of performing in a vascular of a large mammal. The applicant argued on page 7 of the Remarks that Bonadio did not disclosed a "deformable element in a transverse compression", this is not persuasive because in Fig. 3 to Fig. 4, the part 11(b) is deformable, meaning from one shape (Fig. 3) to another shape (Fig. 4), and

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transverse compressed (Figs 4-5). On page 8 of the Remarks, the applicant argued that web 11(b) is not attached to the web 11(a). This is not persuasive because 11(b) is attached, via element 10 and touching each other (Fig. 3). In the 35 USC 103 rejection, the applicant argued that Rhodes discussed endoprosthesis in three pieces to treat aneurisms and stenoses and the device of Rhodes attempts to avoid vascular occlusion and neither Bonadio nor Rhodes discloses "a transverse compression deformable body....". This is not persuasive because first of all, Rhodes disclosed a device to treat aneurisms which has the purpose of preventing rupture of the artery and occluding the blood from bursting out of the artery in the event of rupturing occur. And secondly, Bonadio does disclose "a transverse compression deformable body..." as described above. The applicant argued on page 9 of the Remarks that Janzen discusses not a vascular occlusion device presenting element in a transverse compression. This is not persuasive because Janzen does discuss a device for sealing a puncture wounds for occluding injuries in an artery and the using the sheath and guide structures simply for facilitating implantation of the occlusive device.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809. The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SD

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Supervisory Patent Examiner, Art Unit 3773

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